ingredient in proprietary products. Proprietary food means a food which has not been standardized under PFA Rules, 1955 and Gutka is marketed as proprietary food.

(c) and (d) The draft rules are based on the recommendations of Central Committee for Food Standards, a statuary Committee constituted under PFA Act, 1954, which has representives from States/UTs.

(e) The objections and suggestions have been invited from on the proposed draft amendments which would be considered by the Central Government before the notification is finalized.

Funds for SVIMS and NIMS

1273. SHRIMATI VANGA GEETHA: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether Government have released the funds to Shri Venkateshwara Institute of Medical Sciences (SVIMS) and Nizam's Institute of Medical Sciences (NIMS) in Andhra Pradesh upon the request of the Government of Andhra Pradesh during the current year;

(b) if so, the details thereof; and

(c) if not, the reasons therefor?

THE MINISTER OF HEALTH AND FAMILY WELFARE (DR. ANBUMANI RAMDOSS): (a) and (c) Under the Pradhan Mantri Swasthya Suraksha Yojana (PMSSY), *inter alia* there is a proposal for upgradation of Sri Venkateshwara Institute of Medical Sciences (SVIMS), Tirupati and Nizam's Institute of Medical Sciences (NIMS), Hyderabad, with a total outlay of Rs. 180 Crores approximately, to the level of proposed AIIMS like Institution. The PMSSY Scheme has been cleared by the Expenditure Finance Committee and Committee of Secretaries (COS) and is being processed for placing before Cabinet Committee on Economic Affairs (CCEA) for approval.

Clinical trials

1274. SHRIMATI BRINDA KARAT: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to refer to Starred Question 143 replied in Rajya Sabha on the 2nd December, 2005 and state:

(a) whether there is any provision in Schedule-Y which ensure a level of safety for clinical trials in India in the context of removal of time lag between clinical trials in India and outside; and

(b) whether there is any provision in Schedule-Y which provides compensation or insurance for the clinical trial patients or their families?

THE MINISTER OF HEALTH AND FAMILY WELFARE (DR. ANBUMANI RAMDOSS): (a) and (b) The amended Schedule Y of the Drugs and Cosmetics Act prescribes for submission of adequate safety data for regulatory review, before permission is granted to conduct clinical trials.

Permission to conduct clinical trials for molecules invented outside India is granted only when the same trial is being concurrently conducted in other countries as well.

The amended Schedule Y mandates that Ethics Committees review "Insurance Policy/Compensation for participation and for serious adverse events occurring during the study participation."

The informed consent checklist under Schedule Y also prescribes that the patient should be informed by clinician (Investigator) about "Compensation and/or treatment (s) available to the Subject in the event of a trial-related injury."

According to India Good Clinical Practices (GCP) Guidelines, which must be complied with as per Schedule Y, the sponsor is responsible to indemnify and obtain insurance to cover the cost of treatment in case of any study related harm to patients, and also to provide compensation as prescribed by the laws of the land.

NRHM in Punjab

1275. SHRI VARINDER SINGH BAJWA: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether the National Rural Health Mission is functioning in Punjab;

(b) if so, the details thereof, location-wise; and

(c) the incentives/grants/aids given to the Mission during the last three years, year-wise?

THE MINISTER OF HEALTH AND FAMILY WELFARE (DR. ANBUMANI RAMDOSS): (a) and (b) The National Rural Health Mission (NRHM) is functioning in the state of Punjab. The Mission was launched on 12th April 2005. The first year of Mission is the preparatory phase during which the institutional mechanisms for the implementation of the Mission have been laid down.